

Remarks

Claims 1, 3-7, 11-16, 24-28, and 31-35 were pending in the subject application. By this amendment, claims 1 and 31 have been amended. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1, 3-7, 11-16, 24-28, and 31-35 are currently before the Examiner for consideration. Applicant respectfully submits that these amendments will require no further search on the part of the Examiner and do not constitute new matter. Favorable consideration of the pending claims is respectfully requested.

It should also be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of Applicants' agreement with or acquiescence to, the rejections of record. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, applicant has amended the specification at page 8 and 9 to correct minor typographical errors.

Claims 1, 6, and 7 have been rejected under 35 U.S.C. §102(b) as being anticipated by Sorenson *et al.* (U.S. Patent No. 4,099,528). Specifically, the Office Action contends that the lumens are discreet physical entities separable from the hub. Applicant respectfully traverses this rejection and the supposition that the Sorenson *et al.* lumens are separable.

It is a basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. (See In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984)). Applicant respectfully asserts that the Examiner's position, as stated in the Office Action, is supposition that is not supported or even suggested by the application or claims of Sorenson *et al.* Sorenson *et al.* go into considerable detail about how to remove a bushing positioned between the catheters and used to facilitate venapuncture. But, there is no mention or suggestion by Sorenson *et al.* that the hub is also removable from the catheters, in any way. With regard to the figures in Sorenson *et al.*, relied upon by the Office Action, applicant would like to point out that they show no indication of how the

interior lumen could be removed from the exterior lumen, particularly since the proximal end is illustrated and described as being flush with and opening “into a diametrically enlarged bore” that facilitates fluid communication between the interior lumen and an infusion set (see col. 2, lines 43-49). The Office Action’s flawed observation that the Sorenson *et al.* hub could be separated from the hemodialysis catheter by pulling with sufficient force to overcome a friction fit hub or by severing one of the lumens from the hub is not taught or even suggested by Sorenson *et al.* and, in fact, would render the Sorenson *et al.* catheter ineffective in fulfilling its intended function. In fact, there is no teaching or suggestion by Sorenson *et al.* regarding how one might re-affix the severed end of the catheter to the hub so that the catheter would be able to function properly without affecting patient outcome.

The subject application discloses a dual-lumen catheter device that can be placed into a patient, via venapuncture, either permanently or for sufficient time to accomplish dialysis of a patient. Claim 1 is clear, and the specification details, that both catheters of the subject invention are attached to a “removable hub.” Claim 1 has been further amended to also clarify that removal of the hub does not entail permanently altering the catheters. According to the subject invention, the interior arterial lumen can be “separated and replaced within the venous lumen” and the entire device reassembled. Unlike Sorenson, this allows the interior arterial lumen of the subject invention to be removed for repair and/or replacement without having to simultaneously remove or disrupt the position of the exterior venous lumen (see page 8, lines 1-6).

In view of the above comments and amendments, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) of claim 1, as well as claims 6 and 7 dependent therefrom.

Claims 3-5, 11-16, 24, 25, 27, 28, and 31-35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sorenson *et al.* in view of Zawacki (U.S. Patent No. 6,758,836). Applicant respectfully traverses this rejection because the addition of Zawacki does not cure the defects of the Sorenson *et al.* reference, as put forth above by applicant. With regard to claims 3-5, Sorenson *et al.* do not teach or even suggest a dual-lumen catheter with a hub removable from both catheters. It is clear that Zawacki discloses a split-tip dual-lumen catheter attached to a hub. However, Zawacki discloses only that the inner lumen can be removed from within the outer lumen through the hub.

Applicant submits that altering the length of the inner catheter does not render both catheters detachable from the hub.

The Office Action then goes on to state that each of claims 11-16, 24, 25, 27, and 28 are unpatentable over Sorenson *et al.* in view of Zawacki. Applicant respectfully traverses this rejection.

As detailed above, Sorenson *et al.* do not meet the limitations of the herein amended claim 1, from which claims 1-16, 24, 25, 27, and 28 depend. The recitation by Zawacki of c-shaped catheter lumens, an inner lumen extending beyond the outer lumen, tapered lumen distal ends, a plurality of shaped apertures at the distal end of the venous lumen, use of thermoplastics, and reinforcing materials, etc. does not cure the defects of Sorenson *et al.*

Claim 31 also stands rejected under 35 U.S.C. §103(a) over Sorenson *et al.* in view of Zawacki. For consistency, applicant has amended claim 31 similarly to claim 1, discussed above. The applicant would like to reiterate that the Sorenson *et al.* catheter and bushing are specifically designed to decrease patient discomfort when being punctured with the catheter. Certainly, the Sorenson *et al.* catheter might be used with the incision method of the subject invention, but it would defeat the fundamental purpose for using the bushing and for the corresponding taper between bushing and the dual lumens.

Regarding the rejection of claims 32, 33, 34, and 35, which depend from claim 31, applicant respectfully maintains that the Sorenson *et al.* reference, alone or in combination with Zawacki, does not teach the claimed method utilizing a catheter with dual lumens that can be removed from a hub and separated from each other. Utilizing a guidewire or changing the location of insertion does not cure these defects of the cited references. Again, Zawacki does not teach or even suggest a catheter wherein both lumens can be removed from a hub and, further, Sorenson *et al.* specifically teaches lumens mounted to a hub, so that a bushing can be utilized in the space between them to provide a smoother surface for venipuncture.

In view of the above comments, applicant respectfully requests reconsideration and withdrawal of the rejection of claims 3-5, 11-16, 24, 25, 27, 28, and 31-35 under 35 U.S.C. §103(a)

Claim 26 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Sorenson *et al.* in view of Davey *et al.* (U.S. Patent No. 6,595,966). Applicant respectfully traverses this rejection because the addition of a therapeutic agent as disclosed by Davey *et al.* does not cure the

defects of Sorenson *et al.* as detailed above. Reconsideration and withdrawal of this rejection of claim 26 under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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